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Registration Decision

German Cockroach Extract

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Registration Decision for German Cockroach Extract

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and in accordance with the Pest Control Products Regulations, is granting full registration for the sale and use of German Cockroach Extract Technical, Victor Roach Magnet, Victor Roach Trap, and Victor Roach Trap and Monitor, all containing the technical grade active ingredient German Cockroach Extract, for indoor uses to control German cockroaches.

An evaluation of available scientific information found that, under the approved conditions of use, the end-use products have value and do not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the Consultation Document[1]: *Proposed Registration Decision—German Cockroach Extract* (PRD2007-08). This Registration Decision[2] describes this stage of the PMRA's regulatory process for German Cockroach Extract and summarizes the Agency's decision and the reasons for it. This decision is consistent with the proposed registration decision stated in PRD2007-08.

For more details on the information presented in this Registration Decision, please refer to PRD2007-08 which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration[3]. The Act also requires that products have value[4] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

What Is German Cockroach Extract?

German Cockroach Extract is a chemical extract that contains many different chemical compounds and is derived from feces-contaminated substrates in German cockroach colonies. German Cockroach Extract is used in the manufacture of impregnated lures that are installed within cockroach traps. The various cockroach traps using the German Cockroach Extract lures are the end-use products.

Health Considerations

Can Approved Uses of German Cockroach Extract Affect Human Health?

German Cockroach Extract Technical, Victor Roach Magnet, Victor Roach Trap, and Victor Roach Trap and Monitor are unlikely to affect your health when used according to the label directions.

When assessing the health risks of German Cockroach Extract Technical, Victor Roach Magnet, Victor Roach Trap, and Victor Roach Trap and Monitor, the PMRA considers two key factors: the toxicity of the products and the levels to which people may be exposed.

The active ingredient, German Cockroach Extract, contains many substances that are produced by the German cockroach (*Blatella germanica*). These substances are present in buildings that currently have, or have recently had, a German cockroach infestation. The use of German Cockroach Extract is not expected to increase human exposure to these substances.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Since there are no uses of German Cockroach Extract on food or feed crops, the likelihood of residues contaminating food is negligible.

Occupational Risks From German Cockroach Extract

Occupational risks are not of concern when German Cockroach Extract Technical, Victor Roach Magnet, Victor Roach Trap, and Victor Roach Trap and Monitor are used according to the label directions, which include protective measures.

Pesticide applicators or domestic users placing traps containing German Cockroach Extract impregnated lures will not be exposed to the active ingredient. The lures are attached to the inside of the traps during manufacturing where they are not available for direct exposure to applicators or bystanders.

The postapplication exposure risks to human health are negligible because the amount of active ingredient formulated into each trap is small (0.125 mg). As well, the way in which the active ingredient is formulated into the end-use products will not allow for significant amounts of human exposure to the German Cockroach Extract.

Environmental Considerations

What Happens When German Cockroach Extract Is Introduced Into the Environment?

Environmental risks associated with the use of German Cockroach Extract are of negligible concern.

The end-use products Victor Roach Magnet, Victor Roach Trap, and Victor Roach Trap and Monitor are intended for indoor use (e.g. in kitchens, bathrooms, etc.) and contain only a small amount of German Cockroach Extract. Therefore, only negligible amounts of German Cockroach Extract will enter the environment. Also, German Cockroach Extract is a natural substance and is expected to readily break down in the environment.

Value Considerations

What Is the Value of German Cockroach Extract?

German Cockroach Extract has value in improving trap catches of German cockroaches when incorporated as a lure into the end-use products Victor Roach Magnet, Victor Roach Trap, and Victor Roach Trap and Monitor.

German Cockroach Extract is attractive to German cockroaches, to the extent that they tend to remain in areas where it is present. As a result of this tendency, German cockroaches are more likely to be captured in traps baited with German Cockroach Extract than in unbaited traps. Therefore, traps used to monitor or control German cockroach populations may be more effective when baited with lures containing German Cockroach Extract.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

As human and environmental exposure to German Cockroach Extract is negligible due to the design of the traps and the small amount of active ingredient used, the risk-reduction measures on the labels of German Cockroach Extract Technical, Victor Roach Magnet, Victor Roach Trap, and Victor Roach Trap and Monitor are acceptable and no further additional risk-reduction measures are required.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, www.pmra-arla.gc.ca/english/pubreg/reconsideration-e.html) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra_infoserv@hc-sc.gc.ca).

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[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

1.0 Chemistry Assessment

PMRA Identification Number	Reference
Technical Grade Active Ingredient	
1268801	Product Identification, DACO: 2.1, 2.2
1268802	2003, Cockroach Pheromone Lure: Product Identity and Composition, Beginnng Materials, Production Process, Formation of Impurities, none, DACO: 2.11.1,2.11.2,2.11.3,2.11.4,2.3,2.3.1,2.4,2.5,2.6,2.7,2.8,2.9
1268803	2003, Confidential Attachment to Cockroach Pheromone Lure: Product Identity and Composition, Beginning Materials, Production Process, Formation of Impurities, none, DACO:2.11.1, 2.11.2, 2.11.3, 2.11.4, 2.3, 2.3.1, 2.4, 2.5, 2.6, 2.7, 2.8,2.9
1268804	2003, Cockroach Pheromone Lure: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Certified Limits, none, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4
1268805	2003, Confidential Attached to Cockroach Pheromone Lure: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Certified Limits, none, DACO: 2.12.1,2.13.1,2.13.2,2.13.3,2.13.4
1268806	2003, Cockroach Pheromone Lure: Request to Waive the Requirements for Information on Certain Physical and Chemical Properties of the German Cockroach Pheromone, none, DACO: 2.14.1, 2.14.10, 2.14.11, 2.14.12, 2.14.13, 2.14.14, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6
1268807	Sample (Batch Data), DACO: 2.15
End-use Products	
1050822	2003, Cockroach Pheromone Lure: Product Identity and Composition, Beginning Materials, Production Process, Formation of Impurities., DACO: 3.2
1050823	2003, Confidential Attachment to Cockroach Pheromone Lure: Product Identity and Composition, Beginning Materials, Production Process, Formation of Impurities., DACO: 3.2

1050824	2003, Cockroach Pheromone Lure: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Certified Limits., DACO: 3.3
1050825	2003, Confidential Attached to Cockroach Pheromone Lure: Analysis and Certification of Product Ingredients, Certification of Limits, Analytical Method to Certified Limits., DACO: 3.3
1050826	2003, Cockroach Pheromone Lure: Request to Waive the Requirements for Information on Certain Physical and Chemical Properties of the German Cockroach Pheromone., DACO: 3.5
1050828	Product Identification., DACO: 3.1

2.0 Impact on Human and Animal Health

PMRA Identification Number	Reference
1324828	2006, CBI Reference Document - Response for DACO 4.1, N/A, MRID: N/A, DACO: 4.1
1324877	2006, CBI Reference Document - Response for DACO 5.1, N/A, MRID: N/A, DACO: 5.1

3.0 Impact on the Environment

PMRA Identification Number	Reference
1051535	Cockroach pheromone lure: Request to waive the requirements for ecological effects testing on the German cockroach pheromone. Report Date: 12-December-2003. 5 pages. DACO 9.1.
1051536	Comprehensive data summary for German cockroach pheromone technical. 5 pages. DACO 12.7.

5.0 Value

PMRA Identification Number	Reference
1229913	2005. The effectiveness of German cockroach pheromone lure aged 0, 7, 14, 21, 28 & 35 days. WSL-GCPL003. 12 pp. DACO: 10.2.3.3

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

1.0 Impact on Human and Animal Health

PMRA Identification Number	Reference
1418445	Gore, J.C., Schal, C., Cockroach Allergen Biology and Mitigation in the Indoor Environment. Annu. Rev. Entomol. 2007. 52:439-463, DACO: 5.7
1419601	P. A. Eggleston et al., 2001, P. A. Eggleston et al., Ecology and elimination of cockroaches and allergens in the home. J. Allergy Clin. Immunol. 2001; Vol. 107 (3): p.S422-S429, MRID: N/A, DACO: 5.7